

### ***Remarks***

Upon entry of the foregoing amendment claims 2-14 and 77-79 are pending in the application, with claims 2-3, 77, and 79 being the independent claims. Claims 2, 15-76 and 80-107 have been canceled. Claims 2-14 and 77-79 have been amended. Support for the claim amendments may be found in the original claims and throughout the specification. Thus, no new matter is added by way of these amendments, and their entry is respectfully requested.

### **Oath/Declaration**

The Office Action states that the Oath/Declaration was defective because non-initialed and non-dated alterations were made to the oath or declaration with respect to the mailing address of Harry Yim. Applicants have filed concurrently herewith a new declaration that corrects the defects with respect to the mailing address of Harry Yim.

### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1-14 and 77-79 were rejected as being non-compliant with the Written Description Requirement of 35 U.S.C. § 112, first paragraph.

The Office Action indicates that the specification does not include deposit information for JDP674. The deposit information for JDP674 is disclosed in Applicants' specification at paragraph 131.

The Office Action also states that the specification lacks complete deposit information for the deposit of an *E. coli* strain having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* are resistant to infection by bacteriophage Wphi or Mu.

A biological deposit is required when the invention involves a biological material *and* words alone cannot sufficiently describe how to make and use the invention in a reproducible manner. Thus, while access to biological material *may* be necessary to satisfy the statutory requirements for patentability under 35 U.S.C. § 112, “[b]iological material need not be deposited, *inter alia*, if it is known and readily available to the public or can be made or isolated without undue experimentation.” See MPEP § 2404.

In this case, biological material need not be deposited to satisfy 35 U.S.C. § 112. Applicants’ specification sufficiently describes how to make and use the invention in a reproducible manner such that the invention can be made or isolated without undue experimentation. Applicants’ specification discloses routine methods by which one skilled in the art can easily identify rapid growing microorganisms. See Example 26 at paragraph 142. Using such rapidly growing microorganisms (e.g., deposited strain ATCC 9637), those of ordinary skill in the art can, as a matter of routine experimentation, identify those that are resistant to bacteriophage Wphi or Mu, or can create derivatives thereof that are resistant to bacteriophage Wphi or Mu. Applicants demonstrated the use of routine techniques to construct a Mu bacteriophage resistant strain of rapidly growing bacteria (i.e., deposited strain JDP674). See Examples 23-25. Likewise, Applicants have used such routine techniques to construct two Wphi bacteriophage resistant strain of

rapidly growing bacteria (i.e., strains BRL3844-10A and BRL3844-15A). See Example 21. Therefor, Applicants' specification clearly describes how to make and use the invention in a reproducible manner such that the invention can be made or isolated without undue experimentation. Accordingly, the claims are in compliance with the Written Description requirement and no biological deposit is required. Applicants therefore request that this claim rejections under 35 U.S.C. § 112 be withdrawn.

### **Rejections Under 35 U.S.C. § 101**

Claims 1-14 were rejected as being non-compliant with the Utility Requirement under 35 U.S.C. § 101.

The Office Action states that the claims recite a product of nature. The claims have been amended to recite "isolated *E. coli*." Applicants respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-14 were rejected as being non-compliant with the requirement under 35 U.S.C. § 112, second paragraph.

The Office Action states that the claims are indefinite for failing to a) spell out the abbreviation *E. coli*, when it used for the first time and b) provide antecedent basis for “said isolated *E. coli*” in claim 1.

The claims have been amended to spell out the abbreviation for *E. coli* the first time it is used in a claim. Claim 1 is canceled thus rendering the insufficient antecedent basis rejection moot. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

***Claim Rejections Under 35 U.S.C. § 102(b)***

Claims 1-14 and 77-79 were rejected as being anticipated by Bloom. Applicants respectfully disagree.

An anticipation rejection under 35 U.S.C. § 102 requires a showing that each limitation of a claim is found in a single reference, practice or device. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984). See also M.P.E.P. 8th ed., § 2131 (rev. 2, May 2004) (“To anticipate a claim, the reference must teach every element of the claim.”).

The claims are drawn towards isolated *E. coli* and compositions *comprising E. coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said *E. coli* are resistant to infection by bacteriophage Wphi or Mu.

Bloom discloses isolated *E. coli* strain W having a rapid growth rate that lacks

endogenous plasmids. However, Bloom does not teach isolated *E. coli* or compositions comprising *E. coli* that are specifically resistant to infection by bacteriophage Wphi or Mu. Therefore, Bloom does not anticipate the present claims and Applicants respectfully request that the rejection under 35 U.S.C § 102 be withdrawn.

***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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